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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,042	07/25/2003	Michael Marquant	RDID 02081 US	4047

7590 04/04/2007  
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EXAMINER
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HYUN, PAUL SANG HWA

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/628,042

Applicant(s)

MARQUANT ET AL.

Examiner

Paul S. Hyun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/24/04</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Title***

The title of the invention is misspelled. "analysing" should be changed to "analyzing".

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "connecting member" recited in claim 9 must be shown or the feature canceled from the claim. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

The abstract of the disclosure is objected to because of grammatical errors.

“analysing” in line 1 should be changed to “analyzing”.

“flat material” in line 2 should be changed to either “a flat material” or “flat materials”.

Corrections are required. See MPEP § 608.01(b).

***Claim Objections***

Claims 1, 22 and 24 are objected to because of the following informalities:

“analysing” should be changed to “analyzing”.

Claim 1 is objected to because of the following informalities:

“flat material” in line 4 should be changed to either “a flat material” or “flat materials”.

Appropriate corrections are required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The term "foil mask" does not appear to be a term that is well-known in the art. The Specification also does not provide a clear definition. Therefore, the scope of the limitation "foil mask" is unclear.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim does not set forth the step(s) of the method. Because the claim does not recite any steps for achieving the method, the scope of the claim is uncertain. Consequently, the claim will not be examined on the merits.

It should be noted that the device claims and claim 23 may be subject to restriction once the steps of the method are positively recited.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10, 15-17, 19-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ekström et al. (US 5,376,252).

Ekström et al. disclose a microfluidic device and a method for using the device to analyze biological fluid samples (see Fig. 7A). The device comprises vertically alternating layers 2 and 3 such that a plurality of channels 4 defined by recesses/gaps in layer 3 are stacked on top of one another. Layer 3 defines the sidewalls of the

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channels and layer 4 defines the top and bottom walls of the channels. The channels comprise an inlet 14 and an outlet 15. The channels may be provided with transparent windows for observing the fluid sample within the channel (see lines 30-60, col. 9). The base layer 2 may be made from electrically insulating foil (see lines 60-65, col. 3) and the stacked layers may be glued together to facilitate adhesion (see lines 60-65, col. 6).

With respects to claim 19, it should be noted that the control site is limited by the recitation of the intended use of the control site rather than what the control site actually comprises. The limitation "for checking the filling... control site" do not further limit the stricture of the control site.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5, 6, 9, 19, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. (US 2002/0079219 A1) in view of Ekström et al.

Zhao et al. disclose a microfluidic device for conducting electrochemical analysis of liquid samples (see Fig. 3C and Abstract). The device comprises microfluidic channel 99 formed between layers 92 and 94. The microfluidic channel is lined with a layer of electrode 96 (see [0090]) wherein the electrode can be made from conventional electrode materials such as gold (see [0071]). The electrode extends beyond the layers that define the microfluidic channel (see Figs. 1 and 2). The microfluidic channel leads to a measuring site where electrochemical analysis is conducted (see Fig. 22A and 22B and [0148]). In addition to the electrode, the measuring site can comprise a reference electrode and a counter electrode. The device can also be used to conduct hybridization assays with reagents immobilized at specific sites of the device (see [0103]). The device disclosed by Zhao et al. differs from the claimed device in that it lacks a plurality of stacked layers.

Ekström et al. disclose a microfluidic device (see Fig. 7A). The device comprises vertically alternating layers 2 and 3 such that a plurality of channels 4 defined by recesses/gaps in layer 3 are stacked on top of one another. Ekström et al. disclose that the stacked configuration enables the formation of multi-storied structures and complex channel geometries for conducting reactions and analyses (see lines 25-35, col. 8).

In light of the disclosure of Ekström et al., it would have been obvious to one of ordinary skill in the art to stack the layers of the microfluidic device disclosed by Zhao et al. to form multi-storied microfluidic channel networks. The multi-storied configuration would enable complex reactions and analyses.

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With respects to claim 19, it should be noted that the control site is limited by the recitation of the intended use of the control site rather than what the control site actually comprises. The limitation "for checking the filling... control site" do not further limit the stricture of the control site.

Claims **7 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-3, 5, 6, 9, 19, 24 and 26, and further in view of Akridge et al. (US 5,141,614).

Neither Zhao et al. nor Ekstrom et al. disclose the use of the claimed electrode/counter electrode combination.

Akridge et al. disclose the use of gold working electrode and Ag-AgCl counter electrode combination for detecting dissolved oxygen (see lines 5-10, col. 10).

In light of the disclosure of Akridge et al. it would have been obvious to one of ordinary skill in the art to provide the modified device disclosed by Zhao et al. and Ekstrom et al. with a gold working electrode and Ag-AgCl counter electrode combination to detect dissolved oxygen.

Claims **11 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-3, 5, 6, 9, 19, 24 and 26, and further in view of Lee et al. (US 2003/0141189 A1).

Neither Zhao et al. nor Ekstrom et al. disclose an insulating material.



Lee et al. disclose an electrochemical sensor wherein the electrodes for detecting analytes are covered by an insulating material such that only the tips of the electrodes where the measurement is conducted are exposed (see [0056]).

In light of the disclosure of Lee et al., it would have been obvious to one of ordinary skill in the art to provide an insulating layer to the modified microfluidic device disclosed by Zhao et al. and Ekstrom et al. such that only the parts of the electrodes where the measurements are made are exposed. The insulating layer would provide more accurate measurements.

Claims **12, 13, 27 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. and Lee et al. as applied to claims 11 and 25, and further in view of Oloman et al. (US 4,118,305).

Neither Zhao et al., Ekström et al. nor Lee et al. disclose a porous, hydrophilic insulating material.

Oloman et al. disclose an electrochemical device for conducting reactions wherein the device comprises an electrode, a counter electrode and a porous, hydrophilic insulating material separating the two electrodes (see claim 1). The porous insulating material permits free flow of liquid between the electrodes while providing electrical insulation between the electrodes.

In light of the disclosure of Oloman et al., it would have been obvious to one of ordinary skill in the art to provide a hydrophilic, porous insulating layer between the working and the counter electrodes of the modified microfluidic device disclosed by

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Zhao et al. and Ekstrom et al. so that flow of liquid between the electrodes is permitted while providing electrical insulation between the electrodes.

Claim **14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-3, 5, 6, 9, 19, 24 and 26, and further in view of Stapleton et al. (US 5,922,604).

Neither Zhao et al. nor Ekstrom et al. disclose that the immobilized reagents are dry.

Stapleton disclose a microfluidic device comprising reagents immobilized to the surface of the microfluidic channels wherein the reagents are dry (see lines 40-50, col. 11).

In light of the disclosure of Stapleton et al., it would have been obvious to one of ordinary skill in the art to provide dried reagents to the modified device disclosed by Zhao et al. and Ekstrom et al. so that the reagents can be stored without expiring.

Claim **18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-3, 5, 6, 9, 19, 24 and 26, and further in view of Weigl et al. (US 2001/0027745 A1).

Neither Zhao et al. nor Ekstrom et al. disclose a vent.

Weigl et al. disclose a microfluidic device comprising vents (see [0100]). The vents allow directional flow of fluids.

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In light of the disclosure of Weigl et al., it would have been obvious to one of ordinary skill in the art to provide vents to the modified device disclosed by Zhao et al. and Ekstrom et al. so that fluid flow can be controlled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH  
3/30/07

  
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